

REMARKS

Claims 1-73 are pending, and claims 1-4, 6-14, 22-24, 26-39, and 48-73 are currently under consideration. Applicants cancel, without prejudice, claims 15-21, 34, 36-47, 51-55, 64, 66, and 70-73. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1-2. Claims 1-4, 6-14, 22-24, 26-39, and 48-73 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse this rejection and maintain that the rejection is moot in light of the amended claims.

Applicants maintain the arguments of record, and contend that the previously pending claims are enabled throughout their scope. The specification provided a range of working examples, both *in vitro* and *in vivo*, which provided one of skill in the art ample guidance to practice the claimed invention. Additionally, the specification provided an extensive number of prophetic examples to further guide the skilled artisan in the practice of the claimed invention. Finally, Applicants have provided post filing evidence to further support Applicants' contention that prophetic embodiments disclosed in the application do, in fact, work in the manner that Applicants outlined in detail in the specification. In light of Applicants' working examples, prophetic examples, detailed guidance, and post-filing evidence, Applicants maintain that the previously pending claims are enabled throughout their scope.

Applicants note that in the previous Office Action, the Examiner indicated subject matter that he considers to be in compliance with the requirements under 35 U.S.C. 112, first paragraph. Specifically, the Examiner indicated that Applicants have enabled compositions comprising and compositions consisting essentially of (i) an amino acid sequence at least 95% identical to SEQ ID NO: 3, (ii) a bioactive fragment of SEQ ID NO: 3 that includes seven repeats of the hexameric sequence represented in SEQ ID NO: 1, or (iii) a peptide fragment that includes seven repeats of the hexameric sequence represented in SEQ ID NO: 1. Furthermore, the Examiner indicated that Applicants have enabled certain methods of preventing restenosis using any of these pharmaceutical compositions administered to a target site *in vivo*.

To expedite prosecution of claims directed to commercially relevant embodiments of the invention, Applicants have amended the claims to incorporate the Examiner's suggestions. Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope.

Applicants note, however, that the amended claims additionally include elastin-based compositions comprising and consisting essentially of six repeats of the hexameric sequence represented in SEQ ID NO: 1, as well as methods of using such compositions to prevent restenosis. Support for this subject matter is found throughout the specification. Additionally, Applicants enclose herewith the declaration of Dean Li under 35 U.S.C. § 1.132. Briefly, the declaration and accompanying exhibit summarize work that demonstrates that a stent coated with an elastin-based composition including six repeats of the hexameric sequence VGVAPG (SEQ ID NO: 1) inhibited restenosis when placed into rabbit carotid arteries. The ability of the elastin coated stent to inhibit restenosis *in vivo* was assessed by measuring average lumen area twenty-eight days after stent placement, and comparing this average lumen area to that of arteries in which non-elastin coated stents were inserted. Applicants contend that the declaration of Dean Li provides further evidence in support of the amended claims.

Once again, Applicants maintain the arguments of record and contend that the previously pending claims were enabled throughout their scope. Nevertheless, to expedite prosecution, Applicants have amended the claims to more particularly point out certain embodiments of Applicants' invention. Applicants' amendments reflect the suggestions made by the Examiner in the previous Office Action and further incorporate the subject matter supported by the declaration of Dean Li. Applicants' amendments are believed to obviate the rejection and place the pending claims in condition for allowance. Applicants respectfully point out that, in accordance with MPEP 2164.05, when making a determination as to the enablement provided for the claimed invention, the evidence must be considered as a whole. Furthermore, "the evidence provided by the applicant need not be conclusive but merely convincing to one skilled in the art." (MPEP 2164.05). In light of Applicants' amendments, the post-filing *in vivo* evidence supplied by the declaration of Dean Li, and the arguments of record, Applicants contend that this burden has been satisfied. Reconsideration and withdrawal of this rejection are respectfully requested.

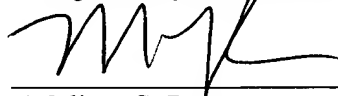
CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. HYDR-P01-002.**

Date: October 15, 2004

Customer No: 28120
Docketing Specialist
Ropes & Gray LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050

Respectfully Submitted,



Melissa S. Rones
Reg. No. 54,408